REMARKS

Applicant respectfully requests continued examination of the present application, pursuant to and consistent with 37 C.F.R. § 1.114, and in light of the remarks which follow.

Claims 1-12, 15-17, 23 and 27-44 are pending. New claim 45 is added. Basis for this claim may be found in the claims and specification as-filed, including at page 10, lines 10-15.

Applicants note with appreciation that the previous objection concerning priority to provisional application 60/445,818, and previous rejection of claims 1-12 and 17-26 under 35 U.S.C. § 112, first paragraph, the rejection of claims 1-6, 9-11, 17, 18 and 29-31 under 35 U.S.C. § 102(b) over WO 97/45140, the rejection of claims 1, 7, 8, and 12 under 35 U.S.C. § 103(a) over the '140 publication, and therejection of claims 1, 3-8, 12, 15, 16, 18, 23, 24, 30 and 31 under 35 U.S.C. § 103(a) over the '128 patent, have been withdrawn.

Applicants respectfully request an interview with Examiner Kim following the submission of this RCE, further to discussion between the Examiner and Applicants' representative.

I. Rejections Under 35 U.S.C. § 103

Claims 1-12, 15-17, 23, 29-32, 41 and 43-44 has been rejected under 35 U.S.C. 103(a) as purportedly unpatentable over U.S. Patent No. 6,194,128, in view of Gordon et al. (*Gastroenterology*, 2001).

The Office argues that the '128 patent discloses that the antibody formulation disclosed therein can stabilize and increase shelf life of any antibody formulation. However, Applicants again submit that conditions and data applicable to one antibody cannot be extrapolated to another without further experimentation. The skilled artisan would not have an expectation of success with the formulations of the '128 patent if natalizumab were substituted in the described formulations. This is the case with regard to monoclonal antibodies, which differ from one another in ways highly relevant to their behavior and efficacy in a formulation. As noted, monoclonal antibodies differ from one another in isoelectric points, solubility, and conditions at

which the monoclonal antibodies will aggregate. Applicants request that this rejection be withdrawn.

II. Rejections Under 35 U.S.C. § 112

Claim 6 stands rejected under 35 U.S.C. 112, first paragraph as purportedly containing subject matter which is not described in the specification. The Office states that the specification and claims do not support the phrase "about 1.7 mg/ml to about 50 mg/ml".

The present specification states that "Antibodies are typically administered to a subject (*e.g.*, a human) at a concentration of about 0.01 mg/mL to about 200 mg/mL. More typically, antibodies range in concentration from about 0.1 mg/mL to about 150 mg/mL. However, instances exist when greater concentrations are required to be administered to a patient, *e.g.*, about 15 to about 200 mg/mL, more preferably about 15 mg/mL to 150 mg/mL, more preferably about 20 to about 50 mg/mL, and most preferably about 20 mg/mL and any integer value in between." See specification at page 10, lines 10-15. Furthermore, the specification discloses dosages of antibodies including 1.7 mg/ml, 5.0 mg/ml, 20 mg/ml, and 50 mg/ml, including at claim 32 as filed. Thus, Applicants submit that a range of 1.7 mg/ml to about 50 mg/ml of natalizumab is contemplated by the present specification. Applicants request that this rejection be withdrawn.

CONCLUSION

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this paper, or the application in general, the Examiner is respectfully urged to telephone Applicants' undersigned representative so that prosecution of this application may be expedited.

Respectfully submitted,

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